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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,664	03/20/2006	Jonathan Robert Rhoades	8502-US	4631

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EXAMINER	
OLSON, ERIC	

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
01/04/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary	Application No.	Applicant(s)	
	10/572,664	RHOADES ET AL.	
	Examiner	Art Unit	
	ERIC S. OLSON	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12, 13, 16-21, 24, and 27-31* is/are pending in the application.

4a) Of the above claim(s) *27* is/are withdrawn from consideration.

5)☒ Claim(s) *24* is/are allowed.

6)☒ Claim(s) *12, 13, 16-21, and 28-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This office action is a response to applicant's communication submitted August 31, 2009 wherein claims 12, 13, 16, 18, 28, 29, and 31 are amended and claim 25 is cancelled. This application is a national stage application of PCT/EP04/10469, filed September 17, 2004, which claims priority to foreign application GB0321996.1, filed September 19, 2003.

Claims 12, 13, 16-21, 24, and 27-31 pending in this application. Claim 27 is withdrawn from consideration as being directed to non-elected subject matter.

Claims 12, 13, 16-21, 24, and 28-31 as amended are examined on the merits herein.

Applicant's amendment, submitted August 31, 2009, with respect to the rejection of instant claim 31 under 35 USC 102(e) for being anticipated by Ångstrom et al., has been fully considered and found to be persuasive to remove the rejection as claim 31 has been amended to require that the composition contain between 1-15g of chito-oligosaccharides. Therefore the rejection is withdrawn.

Applicant's amendment, submitted August 31, 2009, with respect to the rejection of instant claims 12, 13, 16-18, and 28-30 under 35 USC 102(e) for being anticipated by Patrick et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that the composition contain

proanthocyanidin, lactoferin, linoleic acid, or linolenic acid. Therefore the rejection is withdrawn.

Applicant's amendment, submitted August 31, 2009, with respect to the rejection of instant claim 31 under 35 USC 103(a) for being obvious over Lee et al. in view of Prieto et al., has been fully considered and found to be persuasive to remove the rejection as claim 31 has been amended to require that the composition contain between 1-15g of chito-oligosaccharides. Therefore the rejection is withdrawn.

Applicant's amendment, submitted August 31, 2009, with respect to the rejection of instant claims 12, 16-18, 25, and 28-30 under 35 USC 103(a) for being obvious over Bindels et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that the composition contain proanthocyanidin, lactoferin, linoleic acid, or linolenic acid. Therefore the rejection is withdrawn.

Applicant's amendment, submitted August 31, 2009, with respect to the rejection of instant claims 12, 13, 16-18, 25, and 28-30 under 35 USC 102(b) for being anticipated by Tuohy et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that the composition contain proanthocyanidin, lactoferin, linoleic acid, or linolenic acid. Therefore the rejection is withdrawn.

Applicant's amendment, submitted August 31, 2009, with respect to the rejection of instant claims 19-21 under 35 USC 103(a) for being obvious over Tuohy et al. in view of Prieto et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that the composition contain proanthocyanidin, lactoferin, linoleic acid, or linolenic acid. Therefore the rejection is withdrawn.

Applicant's amendment, submitted August 31, 2009, with respect to the rejection of instant claims 19-21 under 35 USC 103(a) for being obvious over Bindels et al. in view of Reid et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that the composition contain proanthocyanidin, lactoferin, linoleic acid, or linolenic acid. Therefore the rejection is withdrawn.

Applicant's amendment necessitates the following new grounds of rejection:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12, 13, 16-18, and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patrick et al. (Reference of record in previous action) in view of Tomita et al. (US patent 5322836, cited in PTO-892)

Patrick et al. discloses a study of the effect of partially hydrolyzed guar gum on constipation in a population of elderly nursing home residents. (p. 913 left column second paragraph) The subjects were administered a composition of 4g PHGG in 4 oz fluid, gradually increased to 12g. (p. 913 left column fifth paragraph) As 4 oz is about 113g and 4 fluid oz of water is about 118g, the lowest 4g dose was administered in a composition comprising about 3.4% of PHGG by weight, and the highest dose of 12g was about 10.1-10.6% PHGG. These amounts are reasonably considered to be “about 2.5 to about 10%” according to the instant claims. Therefore the compositions meet the requirements of the instant claims, and the process of adding the PHGG to the fluid is considered to fall within the methods of claims 28-30. Although Patrick et al. does not

explicitly disclose that the compositions are for inhibiting or treating enteral infections of pathogenic bacteria, this property is inherent in any composition containing the recited ingredients. Furthermore administering said compositions to a subject qualifies as a method of reducing and inhibiting invasion or infection of a pathogenic bacteria in any mammal it is administered to, as said mammal will have a reduced likelihood of contracting an enteric bacterial infection. Patrick et al. does not disclose administering a composition further containing lactoferrin.

Tomita et al. discloses compositions containing bovine lactoferrin which can be used to promote proliferation of *Bifidobacteria* in vivo, for example as drugs or foods. (column 2 lines 36-62) Tomita et al. also discloses that *Bifidobacteria* are useful for treating conditions including constipation. (column 1 lines 21-28) Thus one of ordinary skill in the art would conclude that lactoferrin can be used to treat constipation by increasing the population of *Bifidobacteria*.

It would have been obvious to one of ordinary skill in the art at the time of the invention to add lactoferrin to the partially hydrolyzed guar gum compositions of Patrick et al. One of ordinary skill in the art would have been motivated to do so because both lactoferrin and PHGG are shown to be useful for the same purpose, namely treating constipation. One of ordinary skill in the art would reasonably have expected success because it is ordinary and routine in the art to combine two active agents known to be useful for treating the same condition.

Therefore the invention taken as a whole is *prima facie* obvious. Because Applicant's amendment necessitated this new ground of rejection, the rejection is made **FINAL**.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (Reference of record in previous action) in view of Lesens et al. (US patent 6399124, cited in PTO-892)

Lee et al. discloses the growth of bacterial cultures in the presence of chitooligosaccharides. (p. 320 left column paragraph 4 - right column paragraph 2) The chitoligosaccharides stimulate the growth of bifidobacteria. (p. 321 right paragraph section 3.3) Lee et al. does not disclose a method of treating pathogenic bacteria-associated disorders in a mammal by administering a composition comprising 1-15g of chito-oligosaccharides.

Lesens et al. discloses a frozen desert containing probiotic bacteria for treating gastrointestinal disorders. (column 2 lines 20-36) The probiotic microorganism can include several species of *Bifidobacteria*. (column 2 lines 44-65) The bacteria are capable of excluding pathogenic bacteria from intestinal cells and allowing the immune system to react more strongly against external aggression. (column 3 lines 1-13) The frozen dessert contains a support or coating comprising fibers, for example oligosaccharides, which promote the growth of the probiotic. (column 4 lines 30-52) Fibers can be present in an amount up to 10g. (column 5 lines 15-29)

It would have been obvious to one of ordinary skill in the art at the time of the invention to use from 1-10g of the chito-oligosaccharides of Lee et al. in a bifidobacteria-containing probiotic composition according to Lesens et al., and to administer this composition to a patient suffering from a bacterial enteric infection. One of ordinary skill in the art would have been motivated to do so because Lesens et al. already discloses that the compositions contain up to 10g of prebiotic fibers to promote the growth of the probiotic organism. One of ordinary skill in the art would reasonably have expected success because Lesens et al. discloses that these formulations can protect intestinal cells against pathogenic bacteria.

Therefore the invention taken as a whole is *prima facie* obvious. Because Applicant's amendment necessitated this new ground of rejection, the rejection is made **FINAL**.

Claims 12-13, 16-21, and 28-30 are rejected under 35 U.S.C. 103(b) as being obvious over Tuohy et al. (of record in previous action) in view of Tomita et al. (US patent 5322836, cited in PTO-892)

Tuohy et al. discloses a study of the effects of PHGG (partially hydrolyzed guar gum) and FOS (fructooligosaccharide) on gut microflora in humans. (p. 342, right column second paragraph - p. 343 right column first paragraph) The PHGG was administered as biscuits that contained 11% PHGG. This amount is reasonably considered to be "about 10%" as recited in the instant claims. This study constitutes a method comprising administering PHGG to subjects according to the instant claims.

Furthermore the prebiotics were supplied as biscuits which are reasonably considered to be a pharmaceutical or nutritional composition according to the claimed invention. Subjects receiving the prebiotic treatment increased the levels of *bifidobacteria* in their intestines. (p. 344, left column and tables 1 and 2) Although Tuohy et al. does not explicitly disclose compositions for inhibiting or treating enteral infections of pathogenic bacteria, this property is present for any composition containing the recited ingredients. Furthermore administering said compositions to a subject inherently reduces and inhibits invasion or infection of said pathogenic bacteria in any mammal it is administered to, as said mammal will have a reduced likelihood of contracting an enteric bacterial infection. Tuohy et al. does not disclose a composition further comprising lactoferrin.

Tomita et al. discloses compositions containing bovine lactoferrin which can be used to promote proliferation of *Bifidobacteria* in vivo, for example as drugs or foods. (column 2 lines 36-62) Tomita et al. also discloses that *Bifidobacteria* are useful for treating conditions including infectious diseases and growth inhibition against harmful intestinal microorganisms. (column 1 lines 21-28) Thus one of ordinary skill in the art would conclude that lactoferrin can be used to inhibit growth of harmful organisms in a patient having an enteric bacterial infection by increasing the population of *Bifidobacteria*.

It would have been obvious to one of ordinary skill in the art at the time of the invention to add lactoferrin to the partially hydrolyzed guar gum compositions of Tuohy et al. and to administer this composition to a mammal suffering from an a pathogenic

bacterial intestinal disorder. One of ordinary skill in the art would have been motivated to do so because both lactoferrin and PHGG are shown to be useful for the same purpose, namely promoting growth of *Bifidobacteria*, and because Tomita et al. discloses that *Bifidobacteria* can be used to treat diarrhea, infectious diseases and harmful gastrointestinal microorganisms. One of ordinary skill in the art would reasonably have expected success because it is ordinary and routine in the art to combine two active agents known to be useful for the same purpose.

Therefore the invention taken as a whole is *prima facie* obvious. Because Applicant's amendment necessitated this new ground of rejection, the rejection is made **FINAL**.

Claims 12-13, 16-18, and 28-30 are rejected under 35 U.S.C. 103(b) as being obvious over Tuohy et al. (of record in previous action) in view of Russell et al. (PCT international publication WO01/17365, reference included with PTO-892)

Tuohy et al. discloses a study of the effects of PHGG (partially hydrolyzed guar gum) and FOS (fructooligosaccharide) on gut microflora in humans. (p. 342, right column second paragraph - p. 343 right column first paragraph) The PHGG was administered as biscuits that contained 11% PHGG. This amount is reasonably considered to be "about 10%" as recited in the instant claims. This study constitutes a method comprising administering PHGG to subjects according to the instant claims. Furthermore the prebiotics were supplied as biscuits which are reasonably considered to be a pharmaceutical or nutritional composition according to the claimed invention.

Subjects receiving the prebiotic treatment increased the levels of *bifidobacteria* in their intestines. (p. 344, left column and tables 1 and 2) Although Tuohy et al. does not explicitly disclose compositions for inhibiting or treating enteral infections of pathogenic bacteria, this property is present for any composition containing the recited ingredients. Furthermore administering said compositions to a subject inherently reduces and inhibits invasion or infection of said pathogenic bacteria in any mammal it is administered to, as said mammal will have a reduced likelihood of contracting an enteric bacterial infection. Tuohy et al. does not disclose a composition further comprising lactoferrin.

Russell et al. discloses a method of improving the condition of the skin and coat of a pet by administering a nutritional agent which promotes the growth of bifido and lactic acid bacteria in the gastrointestinal tract of the pet. (p. 2 lines 1-8) The nutritional agent includes prebiotic fibers, such as oligosaccharides, and a probiotic microorganism. (p. 4 line 10-17) Probiotic microorganisms include several *Bifidobacterium* species. (p. 5 lines 9-10) The compositions can also contain a prebiotic oligosaccharide and a linolenic acid rich oil. (p. 7 lines 14-17) Several examples are given on pp. 8-12 in which dogs are administered the aforementioned compositions to improve the condition of their skin or coat.

It would have been obvious to one of ordinary skill in the art at the time of the invention to administer to dogs a composition containing about 10% PHGG according to Tuohy et al. and further comprising linolenic acid. One of ordinary skill in the art would have been motivated to do so because Russell discloses administering a

Bifidobacterium and linolenic acid and one of ordinary skill in the art would have reasonably expected that promoting the growth of the probiotic organism using PHGG as described by Tuohy et al. would improve the beneficial effect of the compositions of Russell. One of ordinary skill in the art would reasonably have expected success because Russell already discloses adding prebiotic oligosaccharides to the composition.

Therefore the invention taken as a whole is *prima facie* obvious. Because Applicant's amendment necessitated this new ground of rejection, the rejection is made **FINAL**.

Conclusion

Claims 12-13, 16-21, and 28-31 are rejected. Claim 24 is seen to be allowable. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. OLSON whose telephone number is (571)272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
12/15/2009

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623